

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO ETHICON WAVE 8 CASES LISTED ON EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF
DAUBERT MOTION TO PRECLUDE OR LIMIT OPINIONS OF
DEFENSE EXPERT CATHERINE MATTHEWS**

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Plaintiffs respectfully request that this Court exclude certain expert testimony proffered by Defendants Ethicon, Inc. and Johnson & Johnson's expert Catherine Matthews, M.D. ("Dr. Matthews"). In support of their motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Catherine Matthews is an Obstetrician/Gynecologist with a subspecialty in Pelvic Floor Medicine and Reconstructive Surgery, and Plaintiffs do not challenge her qualifications as such.¹ Dr. Matthews's general reports set forth opinions on all liability issues with regard to the TVT, including failure to warn and design defect, including opinions on the material properties of polypropylene mesh. However, Dr. Matthews has no experience drafting warnings or designing pelvic mesh devices. Dr. Matthews's experience in the field of Obstetrics and Gynecology does not render all of her opinions admissible. The admission of Dr. Matthews's unfounded opinions is both contrary to law and presents a serious risk of confusing the issues and misleading the jury.² As this Court previously noted, "[j]ust because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and methods to the facts of this case.'"³ Accordingly, Dr. Matthews should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

¹ Wave 8 TVT General Expert Report of Catherine Matthews, M.D. at p. 2 (attached as Ex. B); *see also* Curriculum Vitae of Dr. Matthews (attached as Ex. C).

² *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.'" (citing *Daubert*, 509 U.S. at 596).

³ *Cisson v. C.R. Bard, Inc.*, MDL No. 2187, 2013 U.S. Dist. LEXIS 78061, *42-43 (S.D.W.V. 2013).

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.⁴ The trial judge acts as a gatekeeper for scientific, technical, and other specialized knowledge.⁵

ARGUMENT

I. Dr. Matthews's General Opinions on Warnings Should Be Precluded or Limited.

Dr. Matthews is unqualified to offer opinions on the adequacy of the Ethicon TVT Warnings, including the Instructions for Use (“IFU”). First, Dr. Matthews has never drafted an IFU.⁶ Nor has she provided input to a medical device company on what information needs to be included in an IFU.⁷ Further, she admits in her report that her opinions about the adequacy of the TVT IFU are based on her personal experience, discussion with colleagues, and review of selective medical literature, instead of any formal analysis or study to reliably determine what risks of the TVT were known to physicians—other than her general assumption of what is known through traditional surgical training.⁸ Such testimony lies at the heart of what *Daubert* and its progeny have found inadmissible.

⁴ See *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony).

⁵ See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 141 (1999).

⁶ See Matthews 3/24/2016 Dep. at 71:15-20 (attached as Ex. D).

⁷ *Id.*

⁸ See Ex. B at 25.

This Court exercises its “gatekeeping” function to ensure that expert testimony is both relevant and reliable. FED. R. EVID. 702; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). This obligation applies to all types of expert testimony, not merely scientific analysis. *Kumho Tire*, 526 U.S. at 149; *Holsesapple v. Barrett*, No. 00-1537, 2001 WL 208490, at *1 (4th Cir. 2001). While an expert urologist or pelvic floor surgeon may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). Dr. Matthews does not possess the additional expertise to offer expert testimony about what an IFU should or should not include, and therefore her testimony regarding these issues should be excluded.

Dr. Matthews is not an expert on what risk information medical device manufacturers are required to put in IFUs. She has never written an IFU. She is not an expert on FDA regulations or device warnings. In fact, she believes that manufacturers of medical devices are only required to list generalities of risks associated with the use of their devices in the accompanying IFU.⁹

Dr. Matthews states in her report that she is familiar with physicians’ use of and reliance on IFUs, and she uses this as part of the basis for her opinion that the TVT IFU are adequate.¹⁰ However, Dr. Matthews has never done a survey or used any formal methodology to determine what physicians do or do not know with regard to pelvic mesh devices. Dr. Matthews minimizes the importance of IFUs by placing a greater emphasis on medical literature as the source of information for risks associated with the use of pelvic mesh products, instead of the

⁹ See Ex. D at 73:22-74:4

¹⁰ See Ex. B at 25.

manufacturer.¹¹ Dr. Matthews states that she has personally treated only one patient that experienced pain after being implanted with a TVT.¹² She has never done any kind of formal analysis to determine what percentage of mesh users knew that pain or chronic pain was a potential risk of the pelvic mesh devices. This is an example of Dr. Matthews using her own personal observations and limited review of medical literature without any formal methodology to form opinions regarding the adequacy of the IFU for the TVT. Since Dr. Matthews is relying on what physicians commonly knew about the risks of the devices as a component of her opinion that the IFUs were adequate—yet she cannot state what percentage of physicians knew about particular risks—then she cannot testify reliably as to whether the IFUs were adequate. Dr. Matthews substitutes her own beliefs about what pelvic floor surgeons know or should know as the basis for her opinions without any formal methodology to support her opinions.

Dr. Matthews's opinions that pelvic floor surgeons knew all the risks associated with pelvic mesh devices appear to be based on her personal conviction that any doctor who reads a core textbook in gynecology or urology knows of the risks of complications of pelvic mesh. However, she has no objective evidence for this conclusion, and it is purely speculation, as she has conducted no inquiry into what risks doctors who use the pelvic mesh devices actually know. Dr. Matthews's testimony on the adequacy of Defendants' warnings should be excluded because it is based on no objective criteria. It is based on Dr. Matthews's personal belief that all surgeons have reviewed and retained information in certain textbooks and other materials.

Federal courts agree that *ipse dixit* opinions—which are justified solely by the fact that the expert holds them—are inadmissible. *See, e.g., GE v. Joiner*, 522 U.S. 136, 146 (1997); *see also Pampered Chef v. Alexanian*, 804 F. Supp. 2d 765, 794 (N.D. Ill. 2011) (“If admissibility could be

¹¹ *Id.*

¹² *See* Ex. D at 75:24-76:2.

established merely by the *ipse dixit* of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong.”).

To be admissible, expert testimony must explain the link between the available evidence or data and the expert’s opinion. *United States v. Mamah*, 332 F.3d 475, 478 (7th Cir. 2001); *see also Cunningham v. Masterwear, Inc.*, No. 1:04-cv-1616-JDT-WTL, 2007 WL 1164832, at *9 (S.D. Ind. Apr. 19, 2007) (“It is not enough for an expert to say this is my data and that is my conclusion without connecting the two.”); *Mid-State Fertilizer Co. v. Exchange Nat. Bank of Chicago*, 877 F.2d 1333, 1390 (7th Cir. 1989) (“An opinion has a significance proportioned to the sources that sustain it.”).

Dr. Matthews testified that she was provided R&D files from Ethicon employees at their discretion, but she cannot recall which files were provided.¹³ She further testified that she would never rely on a medical device manufacturer’s answers to specific questions about use, complications, or indications because it could be biased, and those in the medical field must rely on their training or colleagues for such information.¹⁴ Again, Dr. Matthews states this opinion without presenting any reliable methodology used to determine what other pelvic floor surgeons know. Given that Dr. Matthews’s testimony indicates she did not link her theory of what other surgeons know about the risks associated with the use of the TVT to her opinion that the TVT IFU are adequate, the Court should prohibit this opinion under *Daubert*.

II. Dr. Matthews’s General Opinions on the Design and Material Properties of the TVT Should Be Precluded or Limited.

Dr. Matthews does not have any experience in materials engineering and has never designed mesh devices; however, she arbitrarily offers opinions regarding the design and the

¹³ Ex. D at 55:6-56:4.

¹⁴ Ex. D at 57:10:24.

material properties of Ethicon's TVT device.¹⁵ Specifically, she opines that polypropylene is inert, does not undergo mechanical changes or degrade, and that the material properties of polypropylene do not have any clinical significance for patients.¹⁶ Dr. Matthews simply does not have the requisite experience to proffer this opinion. Dr. Matthews's opinions amount to nothing more than assumptions, and therefore are unreliable under *Daubert*.¹⁷

Dr. Matthews is a board certified Obstetrician/Gynecologist with a practice focused on female pelvic floor medicine.¹⁸ Dr. Matthews does not have any specialized education, training, or applicable relevant experience specifically related to the design or material properties of polypropylene mesh devices.¹⁹ In fact, Dr. Matthews has never designed pelvic mesh devices. Dr. Matthews testified that she is not a biomaterials expert and has had no biomaterials training.²⁰

Dr. Matthews conceded in her deposition that she has never performed any material test for polypropylene mesh:

Q. Okay. And as a doctor, you have never been asked or called upon to perform any type of tensile or material test for polypropylene mesh, have you?

A. No.²¹

Despite her lack of education, experience, and training about the design and material properties of polypropylene mesh devices, Dr. Matthews attempts to opine on TVT's design and material properties, including degradation, inertness, weight, porosity, and cut (laser or mechanical).²²

¹⁵ See Ex. D at 34:3-19.

¹⁶ See Ex. B.

¹⁷ *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3(4th Cir., Sept. 8, 1997) (the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); see also *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

¹⁸ See Ex. B at 2; Ex. C.

¹⁹ *Id.*

²⁰ See Ex. D at 104:13-105:8.

²¹ *Id.* at 105:18-21.

²² See Ex. B.

These opinions undoubtedly exceed the bounds of her qualifications and should be precluded under *Daubert*.

III. Dr. Matthews's Opinions about Her Personal Experience Related to the Safety and Efficacy of the TVT Should Be Precluded.

Dr. Matthews should be precluded from testifying about her perceived safety, efficacy, and patient satisfaction rates with the TVT from her practice, as those opinions are entirely unsupported by any reliable methodology, nor have they been subject to peer review. This court has already ruled that an expert cannot relate precise statistics based on their own assurances that those statistics are reliable. *In re: Ethicon, Inc.*, No. 2327, 2016 WL 4542054, at *4 (S.D.W. Va. Aug. 30, 2016).

In her report, Dr. Matthews states that of the patients in which she has personally placed a TVT, none have ever experienced a bladder or urethral mesh erosion, retropubic hematoma, vascular or nerve injury, or bowel injury.²³ She further states that she has only treated one patient with retropubic/groin pain following TVT.²⁴ She testified that pain related specifically to the TVT is limited to suprapubic pain and dyspareunia, based upon the literature she has reviewed.²⁵ Dr. Matthews's opinions about patient satisfaction and adverse event rates among her own patients are inappropriate, unsupported, and inadmissible. Her opinions are exactly the kind of foundationless testimony this Court has excluded in the past. Allowing Dr. Matthews to offer an opinion as to her patient satisfaction rate without any reliable methodology to support her conclusion would be confusing and misleading to a jury when considering whether the mesh device in question is defective. Thus, her opinion should be excluded.

²³ See Ex. B at p. 6.

²⁴ *Id.*

²⁵ See Ex. D. at 147:10-17.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court exclude the above opinion testimony from Catherine Matthews, regarding (a) the adequacy of the TVT warnings, (b) opinions regarding the design and scientific properties of the TVT mesh device, and (c) her personal experience related to the safety and efficacy of TVT mesh device.

Dated: October 18, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on October 18, 2018, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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